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PATENT CENTER 1600/2900

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: POONAM SALOTRA, et al.

Serial No.: 10/086,184

Group No.: 1645

Filed: February 27, 2002

Examiner .: --

For: Species-specific PCR Assay for detection of Leishmania Donovani in clinical

samples of Kala-Azar and post Kala-Azar Dermal Leishmaniasis

Attorney Docket No.: U 013891-8

**Assistant Commissioner for Patents** 

Washington, D.C. 20231

Sirs:

### SUBSTITUTE DECLARATIONS

Kindly substitute the attached Three Declarations for the documents previously filed on September 25, 2002.

Respectfully submitted

CLIFFORD J. MASS LADAS & PARRY 26 WEST 61<sup>ST</sup> STREET NEW YORK, NEW YORK 10023 REG. NO. 30,086 (212) 708-1890

### CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 2023

CLIFFORD J. MASS

(Type of print name of person mailing paper)

Date: December 11, 2002

(Signature of person mailing paper)

Practitioner's Docket No. \_

U 013891-8



### Optional Customer No. Bar Code

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PATENT TRADEMARK OFFICE

### COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION, OR C-I-P)

As a below named inventor, I hereby declare that:

### TYPE OF DECLARATION

This declaration is of the following type:

(check one applicable item below)

	[x]	original. design.
NOTE:	With the declarat 714.16,	exception of a supplemental oath or declaration submitted in a reissue, a supplemental oath or tion is not treated as an amendment under 37 CFR 1.312 (Amendments after allowance). M.P.E.P. Section 7 <sup>th</sup> Ed.
	[]	supplemental.
NOTE:	If the dec	claration is for an International Application being filed as a divisional, continuation or continuation-in- lication, do <u>not</u> check next item; check appropriate one of last three items.
	[]	national stage of PCT.
NOTE:	If one of CONTIN	the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL, IUATION OR C-I-P.
NOTE:	declarati	C.F.R. Section 1.63(d) (continued prosecution application) for use of a prior nonprovisional application ion in the continuation or divisional application being filed on behalf of the same or fewer of the inventors the prior application.
	[]	divisional. continuation.
NOTE:	or divisio	n application discloses and claims subject matter not disclosed in the prior application, or a continuation onal application names an inventor not named in the prior application, a continuation-in-part application filed under 37 C.F.R. Section 1.53(b) (application filing requirements-nonprovisional application).
	[]	continuation-in-part (C-I-P).

### INVENTORSHIP IDENTIFICATION

**WARNING:** 

If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

### TITLE OF INVENTION

		<u>cific PCR Assay for detection of Leishmania Donovani in clinical samples of Kala-Azar</u> la-Azar Dermal Leishmaniasis
-		SPECIFICATION IDENTIFICATION
The sp	ecifica	tion of which:
		(complete (a), (b), or (c))
(a)	[]	is attached hereto.
NOTE:	with a	pllowing combinations of information supplied in an oath or declaration filed on the application filing date specification are acceptable as minimums for identifying a specification and compliance with any one of the velow will be accepted as complying with the identification requirement of 37 C.F.R. Section 1.63:
	declara	"(l) name of inventor(s), and reference to an attached specification which is both attached to the oath or ation at the time of execution and submitted with the oath or declaration on filing;
		"(2) name of inventor(s), and attorney docket number which was on the specification as filed; or
		"(3) name of inventor(s), and title which was on the specification as filed."
		Notice of July 13, 1995 (1177 O.G. 60).
(b)	[x]	was filed on February 27, 2002, [x] as Application No10/086,184 and was amended on (if applicable).
NOTE:	Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 C.F.R. Section 1.67.	
NOTE:	accepta	able as minimums for identifying a specification and compliance with any one of the items below will be a scomplying with the identification requirement of 37 C.F.R. Section 1.63:  (A) application number (consisting of the series code and the serial number, e.g., 08/123,456);  (B) serial number and filing date;  (C) attorney docket number which was on the specification as filed:  (D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or  (E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration.  M.P.E.P. § 601.01(a), 7th ed.

(c)	[]	was described and claimed in PCT International Application No filed
		on and as amended under PCT Article 19 on (if any).
		SUPPLEMENTAL DECLARATION (37 C.F.R. Section 1.67(b))
	(0	nplete the following where a supplemental declaration is being submitted)
	[]	I hereby declare that the subject matter of the
		attached amendment amendment filed on
	was pa applica	of my/our invention and was invented before the filing date of the original on, above identified, for such invention.
	ACK	OWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR
specifi	I hereb cation, i	state that I have reviewed and understand the contents of the above-identified luding the claims, as amended by any amendment referred to above.
37, Co	I acknode of Fe	relations, Section 1.56,
		(also check the following items, if desired)
	[]	and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, and
		in compliance with this duty, there is attached an information disclosure statement, in accordance with 37 C.F.R. Section 1.98.
		PRIORITY CLAIM (35 U.S.C. Section 119(a)-(d))
OTE:	37 C.F.R	1.55 Claim for foreign priority.
		(a) An applicant in a nonprovisonal application may claim the benefit of the filing date of one or more prior prior applications under the conditions specified in 35 U.S.C. 119(a) through (d) and (f), 172, and 365(a) and (b).
		(1)(i) In an original application filed under 35 U.S.C. 111(a), the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the fling date of the prior foreign application. This time period is not extendable. The claim must identify the foreign application for which priority os claimed, as well as any foreign application for the same subject matter and

(ii) In an application that entered the national stage from an international application after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT."

having a filing date before that of the application for which priority is claimed, by specifying the application number, country (or intellectual property authority), day, month, and year of its filing. The time period in this paragraph does not apply to an application for a design patent.

(2) The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. 119(b) or PCT Rule 17 must, in any event, be filed before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by the processing fee set forth in § 1.17(i), but the patent will not include the priority claim unless corrected by a certificate of correction under 35 U.S.C. 255 and § 1.323.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

### (complete (d) or (e))

(d)	[x]	no such applications have been filed.
(e)	[]	such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

# PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. SECTION 119(a)-(d)

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING DAY, MONTH, YEAR	PRIORITY CLAIMED UNDER 35 USC 119
			[]YES []NO
			[ ]YES [ ]NO

### CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S) (35 U.S.C. Section 119(e))

(33 0.3.6. 3661011 119(6))

NOTE: 35 U.S.C. 119(e)(1) requires that a nonprovisional application be filed within twelve months of the filing date of the provisional application for the nonprovisional application to claim the benefit of the filing date of the provisional application. Under 35 U.S.C. 21(b) and 119(e)(3), if this twelve-month period expires on a non-business day, it is extended to expire on the next business day.

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER	FILING DATE
/	
/	

### CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. SECTION 120

[ ] The claim for the benefit of any such applications are set forth in the attached ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART (C-I-P) APPLICATION.

## ALL FOREIGN APPLICATION(S), *IF ANY*, FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. Section 120.

### **POWER OF ATTORNEY**

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

(list name and registration number)

JOSEPH H. HANDELMAN, 26179

JULIAN H. COHEN, 20302

JOHN RICHARDS, 31053

**WILLIAM R. EVANS 25858** 

RICHARD J. STREIT, 25765

JANET I. CORD, 33778

PETER D. GALLOWAY, 27885

CLIFFORD J. MASS, 30086

RICHARD P. BERG, 28145

CYNTHIA R. MILLER, 34678

(Declaration and Power of Attorney-page 5 of 8) 1-1

### (Check the following item, if applicable)

- [ ] I hereby appoint the practitioner(s) associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.
- Attached, as part of this declaration and power of attorney, is the authorization of the above-named practitioner(s) to accept and follow instructions from my representative(s).

NOTE: "Special care should be taken in continuation or divisional applications to ensure that any change of correspondence address in a prior application is reflected in the continuation or divisional application. For example, where a copy of the oath or declaration from the prior application is submitted for a continuation or divisional application filed under 37 CFR 1.53(b) and the copy of the oath or declaration from the prior application designates an old correspondence address, the Office may not recognize, in the continuation or divisional application, the change of correspondence address made during the prosecution of the prior application. Applicant is required to identify the change of correspondence address in the continuation or divisional application to ensure that communications from the Office are mailed to the current correspondence address. 37 CFR 1.63(d)(4)." Section 601.03, M.P.E.P., 7th Ed

### SEND CORRESPONDENCE TO

Ladas & Parry 26 West 61<sup>st</sup> Street New York, N.Y. 10023 DIRECT TELEPHONE CALLS TO:

(Name and telephone number)

Clifford J. Mass (212) 708-1890

(complete the following if applicable)

Since this filing is a [ ] continuation [ ] divisional there is attached hereto a Change of Correspondence Address so that there will be no question as to where the PTO should direct all correspondence.

### **DECLARATION**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

### SIGNATURE(S)

NOTE:	Carefully indicate the fam	nily (or last) name, as it should appear on t	he filing r	eceipt and all other document.
NOTE:	Each inventor must be identified by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and by his/her residence, post office address and country of citizenship. 37 C.F.R. Section 1.63(a)(3).			
NOTE:	~	parate declarations/oaths provided <u>each</u> de es that a declaration/oath, inter alia, ident ths which each sets forth only the name of t 7,	iiv each in	ventor and promotis the exception of
Full n	ame of sole or first in	ventor		
Poonar (Given	m 1 Name)	(Middle Initial or Name)	<u>.</u>	SALOTRA Family (Or Last Name)
•	tor's signature (X)			/
		Country of Citizenship	India	
Reside	ence C 145, Sarvoday	a Enclave, New Delhi 110017, Indi	a	
		(Same as above)		
1001			<u> </u>	
	-			
Full n	name of second joint i	inventor, if any		
_	n Name)	(Middle Initial or Name)		SREENIVAS Family (Or Last Name)
	itor's signature <u>(X)</u>		-	/
		Country of Citizenship		
Resid	lence <u>C 145, Sarvoday</u>	va Enclave, New Delhi 110017, Ind	ia .	<del></del>
Post	Office Address	(Sāffiē as above)		
		· · · · · · · · · · · · · · · · · · ·		
Full	name of third joint ir	enventor, if any		
Greg (Give	ory en Name)	(Middle Initial or Name)		POGUE Family (Or Last Name)
Inve	ntor's signature <u>(X)</u>	mze		í
Date	(X) 11.06.02	Country of Citizenship	Unite	ed States of America
Resi	dence 419 Trillick Ct.	, Vacaville, California 95688		
Post	Office Address	(Same as above)		
				·

# (check proper box(es) for any of the following added page(s) that form a part of this declaration)

[x]	Signature for fourth and subsequent joint inventors. Number of pages addedl
	* * *
[]	Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. Number of pages added
	* * *
[]	Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 C.F.R. Section 1.47. Number of pages added
	* * *
[ ]	Added page for signature by one joint inventor on behalf of deceased inventor(s) where legar representative cannot be appointed in time. (37 C.F.R. Section 1.47)
	* * *
[]	Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (C-I-P) application.  [ ] Number of pages added
	* * *
[]	Authorization of practitioner(s) to accept and follow instructions from representative.
	(If no further pages form a part of this Declaration, then end this Declaration with this page and check the following item)
	[ ] This declaration ends with this page.

# ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR SIGNATURE BY FOURTH AND SUBSEQUENT INVENTORS THE RESERVE TO THE PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR SIGNATURE BY FOURTH AND SUBSEQUENT INVENTORS

Hiralal (Given Name)	(Middle Initial or Name)	NAKHASI Family (Or Last Name)
Inventor's signature (X)		
	Country of Citizenship	United States of America
Residence 8504 Potomac S	chool Terrace, Potomac, Marylan	d 20854
		·
Full name of fifth joint inve	entor, if any	: .
(Given Name)	(Middle Initial or Name)	Family (Or Last Name)
Date	Country of Citizenship	
Residence		
Post Office Address		
Full name of sixth joint inv	entor, if any	
(Given Name)	(Middle Initial or Name)	Family (Or Last Name)
Inventor's signature		
Date	Country of Citizenship	
Residence		
Post Office Address		

U 013891-8

**PATENT** 

### Optional Customer No. Bar Code



PATENT TRADEMARK OFFICE

### COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION, OR C-I-P)

As a below named inventor, I hereby declare that:

### TYPE OF DECLARATION

This declaration is of the following type:

(check one applicable item below)

	[x]	original. design.
NOTE:	With the declarati 714.16, 7	exception of a supplemental oath or declaration submitted in a reissue, a supplemental oath or ion is not treated as an amendment under 37 CFR 1.312 (Amendments after allowance). M.P.E.P. Section $^{th}$ Ed.
	[]	supplemental.
NOTE:	lf the dec part appl	claration is for an International Application being filed as a divisional, continuation or continuation-in- lication, do <u>not</u> check next item; check appropriate one of last three items.
	[]	national stage of PCT.
NOTE:	lf one of a	the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL, UATION OR C-I-P.
NOTE:	declaration	F.R. Section 1.63(d) (continued prosecution application) for use of a prior nonprovisional application on in the continuation or divisional application being filed on behalf of the same or fewer of the inventors the prior application.
	[]	divisional. continuation.
NOTE:	or divisio	application discloses and claims subject matter not disclosed in the prior application, or a continuation nal application names an inventor not named in the prior application, a continuation-in-part application led under 37 C.F.R. Section 1.53(b) (application filing requirements-nonprovisional application).
	[]	continuation-in-part (C-I-P).

### INVENTORSHIP IDENTIFICATION

WARNING:

If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

#### TITLE OF INVENTION

Spec and r	ies-spec	<u>cific PCR Assay for detection of Leishmania Donovani in clinical samples of Kala-Azar</u> la-Azar Dermal Leishmaniasis
-	2031 ILU	SPECIFICATION IDENTIFICATION
The sr	ecifica	tion of which:
		(complete (a), (b), or (c))
(a)	[]	is attached hereto.
NOTE:	with a	ollowing combinations of information supplied in an oath or declaration filed on the application filing date specification are acceptable as minimums for identifying a specification and compliance with any one of the elow will be accepted as complying with the identification requirement of 37 C.F.R. Section 1.63:
	declara	"(1) name of inventor(s), and reference to an attached specification which is both attached to the oath o ation at the time of execution and submitted with the oath or declaration on filing:
		"(2) name of inventor(s), and attorney docket number which was on the specification as filed: or
		"(3) name of inventor(s), and title which was on the specification as filed."
		Notice of July 13, 1995 (1177 O.G. 60).
(b)	[x]	was filed on February 27, 2002, [x] as Application No. 10/086,184 and was amended on (if applicable).
NOTE:	Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 C.F.R. Section 1.67.	
NOTE:	"The following combinations of information supplied in an oath or declaration filed after the filing date are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 C.F.R. Section 1.63:  (A) application number (consisting of the series code and the serial number, e.g., 08/123,456);  (B) serial number and filing date;  (C) attorney docket number which was on the specification as filed:  (D) title which was on the specification as filed and reference to an attached specification which both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or  (E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration.  M.P.E.P. § 601.01(a), 7th ed.	

(c)	[]	was on	described and claimed in PCT International Application No filed and as amended under PCT Article 19 on (if any).
		SUP	PLEMENTAL DECLARATION (37 C.F.R. Section 1.67(b))
	(	complete	the following where a supplemental declaration is being submitted)
	[]	l here	by declare that the subject matter of the
		[]	attached amendment amendment filed on
	was p appli	part of m	y/our invention and was invented before the filing date of the original bove identified, for such invention.
	ACI	CNOWL	EDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR
specif	I here	by state includin	that I have reviewed and understand the contents of the above-identified g the claims, as amended by any amendment referred to above.
37, Co	I ackr ode of F	nowledge ederal R	e the duty to disclose information, which is material to patentability as defined in egulations, Section 1.56,
			(also check the following items, if desired)
	[]	where	hich is material to the examination of this application, namely, information there is a substantial likelihood that a reasonable Examiner would consider it tant in deciding whether to allow the application to issue as a patent, and
		[]	in compliance with this duty, there is attached an information disclosure statement, in accordance with 37 C.F.R. Section 1.98.
			PRIORITY CLAIM (35 U.S.C. Section 119(a)-(d))
VOTE:	37 C.F.	R. § 1.55 (	Claim for foreign priority.
		"(a) An o foreign o and (b).	applicant in a nonprovisonal application may claim the benefit of the filing date of one or more prior applications under the conditions specified in 35 U.S.C. 119(a) through (d) and (f), 172, and 365(a)
			(1)(i) In an original application filed under 35 U.S.C. 111(a), the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the fling date of the prior foreign application. This time period is not extendable. The claim must identify the foreign application for which priority as claimed, as well as any foreign application for the same subject matter and

which priority os claimed, as well as any foreign application for the same subject matter and having a filing date before that of the application for which priority is claimed, by specifying the application number, country (or intellectual property authority), day, month, and year of its filing. The time period in this paragraph does not apply to an application for a design patent.

(ii) In an application that entered the national stage from an international application after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT."

(2) The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. 119(b) or PCT Rule 17 must, in any event, be filed before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by the processing fee set forth in § 1.17(i), but the patent will not include the priority claim unless corrected by a certificate of correction under 35 U.S.C. 255 and § 1.323.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

### (complete (d) or (e))

(a) (e)	[X]	such applications have been filed. such applications have been filed as follows.
NOTE:	Where check	item (c) is entered above and the International Application which designated the U.S. itself claimed priority item (e), enter the details below and make the priority claim.

# PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. SECTION 119(a)-(d)

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING DAY, MONTH, YEAR	PRIORITY CLAIMED UNDER 35 USC 119
			[]YES []NO
	<del></del>		[]YES []NO

### CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S) (35 U.S.C. Section 119(e))

NOTE: 35 U.S.C. 119(e)(1) requires that a nonprovisional application be filed within twelve months of the filing date of the provisional application for the nonprovisional application to claim the benefit of the filing date of the provisional application. Under 35 U.S.C. 21(b) and 119(e)(3), if this twelve-month period expires on a non-business day, it is extended to expire on the next business day. I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below: PROVISIONAL APPLICATION NUMBER FILING DATE CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) **UNDER 35 U.S.C. SECTION 120** [ ]The claim for the benefit of any such applications are set forth in the attached ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART (C-I-P) APPLICATION. ALL FOREIGN APPLICATION(S), IF ANY, FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. Section 120.

#### POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

(list name and registration number)

JOSEPH H. HANDELMAN, 26179

JULIAN H. COHEN, 20302

JOHN RICHARDS, 31053

**WILLIAM R. EVANS 25858** 

RICHARD J. STREIT, 25765

JANET I. CORD, 33778

PETER D. GALLOWAY, 27885

CLIFFORD J. MASS, 30086

RICHARD P. BERG, 28145

CYNTHIA R. MILLER, 34678

(Declaration and Power of Attorney-page 5 of 8) 1-1

### (Check the following item, if applicable)

- [ ] I hereby appoint the practitioner(s) associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.
- [ ] Attached, as part of this declaration and power of attorney, is the authorization of the above-named practitioner(s) to accept and follow instructions from my representative(s).

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SEND CORRESPONDENCE TO

Ladas & Parry 26 West 61<sup>st</sup> Street New York, N.Y. 10023 DIRECT TELEPHONE CALLS TO: (Name and telephone number)

Clifford J. Mass (212) 708-1890

(complete the following if applicable)

Since this filing is a [ ] continuation [ ] divisional there is attached hereto a Change of Correspondence Address so that there will be no question as to where the PTO should direct all correspondence.

### **DECLARATION**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

### SIGNATURE(S)

IOTE:	Carejully malcule me ju	mily (or last) name, as it should appear on the fi	ling receipt and all other document.		
NOTE:	Each inventor must be identified by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and by his/her residence, post office address and country of citizenship. 37 C.F.R. Section 1.63(a)(3).				
NOTE:	C .: 1 (2/-1/2) magni	eparate declarations/oaths provided <u>each</u> declar ires that a declaration/oath, inter alia, identify ed aths which each sets forth only the name of the e 97,	ich inventor and promotis the execution of		
Full n	ame of sole or first i	nventor			
Poona	m ·	<u>.</u>	SALOTRA		
(Giver	Name)	(Middle Initial or Name)	Family (Or Last Name)		
Inven	tor's signature <u>(X)</u>	- J			
Date (	(X)	Country of Citizenship In	dia		
Resid	ence C 145, Sarvoda	ya Enclave, New Delhi 110017, India			
		(Same as above)	·		
	. 0	·	_ :		
Full r	name of second joint	inventor, if any			
			CD TEXT III (A.C.		
G			SREENIVAS		
G. (Give	n Name)	(Middle Initial or Name)	Family (Or. Last Name)		
		(Middle Initial or Name)	SREENIVAS Family (Or. Last Name)		
	itor's signature <u>(X)</u>		SREENIVAS Family (Or. Last Name)  ndia		
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Inver Date Resid	ntor's signature <u>(X)</u> (X) lence <u>C 145, Sarvoda</u>	Country of CitizenshipI nya Enclave, New Delhi 110017, India (Same as above)	Family (Or Last Name)  ndia		
Inver Date Resid Post Full	ntor's signature (X) (X)  lence C 145, Sarvoda  Office Address  name of third joint i	Country of Citizenship In Inga Enclave, New Delhi 110017, India (Same as above)  inventor, if any	Family (Or. Last Name)  ndia  POGUE		
Inver Date Resid Post Full	ntor's signature (X) (X) lence C 145, Sarvoda Office Address	Country of CitizenshipI nya Enclave, New Delhi 110017, India (Same as above)	Family (Or. Last Name)		
Inver Date Resid Post  Full Greg (Give	ntor's signature (X) (X)  dence C 145, Sarvoda  Office Address  name of third joint in the cory	Country of CitizenshipInya Enclave, New Delhi 110017, India (Sāme as ābove)  inventor, if any  P. (Middle Initial or Name)	Family (Or. Last Name)  ndia  POGUE Family (Or Last Name)		
Inver Date Resid Post  Full Greg (Give	ntor's signature (X) (X)  dence C 145, Sarvoda  Office Address  name of third joint in the cory	Country of CitizenshipInya Enclave, New Delhi 110017, India (Same as above)  inventor, if any  P. (Middle Initial or Name)	POGUE Family (Or Last Name)		
Inverted Date Reside Post Full Greg (Give	ntor's signature (X) (X)  dence C 145, Sarvoda  Office Addréss  name of third joint in the cory en Name) ntor's signature (X)	Country of CitizenshipInya Enclave, New Delhi 110017, India (Sāme as ābove)  inventor, if any  P. (Middle Initial or Name)	POGUE Family (Or Last Name)		
Inverted Post  Full  Greg (Give Inve	ntor's signature (X) (X)  lence C 145, Sarvoda Office Addréss  name of third joint is ory en Name) ntor's signature (X) e (X) dence 419 Trillick C	Country of Citizenship In the state of the state o	Family (Or. Last Name)  ndia  POGUE Family (Or Last Name)		
Inverted Post  Full  Greg (Give Inve	ntor's signature (X) (X)  lence C 145, Sarvoda Office Addréss  name of third joint is ory en Name) ntor's signature (X) e (X) dence 419 Trillick C	Country of CitizenshipInva Enclave, New Delhi 110017, India (Same as above)  inventor, if any  P. (Middle Initial or Name)  Country of CitizenshipInv., Vacaville, California 95688	POGUE Family (Or Last Name)		

# (check proper box(es) for any of the following added page(s) that form a part of this declaration)

[x]	Signature for fourth and subsequent joint inventors. Number of pages addedl
	* * *
[]	Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. Number of pages added-
	* * *
[]	Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 C.F.R. Section 1.47. Number of pages added
	* * *
[]	Added page for signature by one joint inventor on behalf of deceased inventor(s) where lega representative cannot be appointed in time. (37 C.F.R. Section 1.47)
	* * * .
[]	Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (C-I-P) application.  [ ] Number of pages added
	* * *
[]	Authorization of practitioner(s) to accept and follow instructions from representative.
	(If no further pages form a part of this Declaration, then end this Declaration with this page and check the following item)
	[ ] This declaration ends with this page.

Practitioner's	Docket No.	<u>U 013891-8</u>



# ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR SIGNATURE BY FOURTH AND SUBSEQUENT INVENTORS

Full name of fourth joint inve	entor, if any	
Hiralal (Given Name)	(Middle Initial or Name)	NAKHASI Family (Or Last Name)
	Hualal Naki	
Date (X) 11/15/62	Country of Citizenship	United States of America
Residence 8504 Potomac Sc	hool Terrace, Potomac, Maryland	20854
Post Office Address	(Same as above)	
Full name of fifth joint inven	ntor, if any	;
(Given Name)	(Middle Initial or Name)	Family (Or Last Name)
Inventor's signature		
Date	Country of Citizenship	·
Post Office Address		
		:
. •		•
Full name of sixth joint inve	entor, if any	
	(Middle Initial or Name)	
Inventor's signature		
Date	Country of Citizenship	<u> </u>
Residence		
Post Office Address		
		•

(Added Page to Combined Declaration and Power of Attorney for Signature by Fourth and Subsequent Inventors page 1 of 1) 1-2

EXI This declaration ends with this page.

Jamo Murhy 11/15/2002

Regulatory Counsel, CBER, FDA.



### Optional Customer No. Bar Code



#### PATENT TRADEMARK OFFICE

### COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION, OR C-I-P)

As a below named inventor, I hereby declare that:

### TYPE OF DECLARATION

This declaration is of the following type:

		(check one applicable item below)			
	[x]	original. design.			
NOTE:	declara	With the exception of a supplemental oath or declaration submitted in a reissue, a supplemental oath or declaration is not treated as an amendment under 37 CFR 1.312 (Amendments after allowance). M.P.E.P. Section 714.16, 7th Ed.			
	[]	supplemental.			
NOTE:	lf the de part app	eclaration is for an International Application being filed as a divisional, continuation or continuation-in- plication, do <u>not</u> check next item; check appropriate one of last three items.			
	[]	national stage of PCT.			
NOTE:	If one of	the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL, NUATION OR C-I-P.			
NOTE:	declarat	C.F.R. Section 1.63(d) (continued prosecution application) for use of a prior nonprovisional application tion in the continuation or divisional application being filed on behalf of the same or fewer of the inventors in the prior application.			
	[]	divisional. continuation.			
NOTE:	or divisi	n application discloses and claims subject matter not disclosed in the prior application, or a continuation onal application names an inventor not named in the prior application, a continuation-in-part application filed under 37 C.F.R. Section 1.53(b) (application filing requirements-nonprovisional application).			
	[]	continuation-in-part (C-I-P).			

### INVENTORSHIP IDENTIFICATION

**WARNING:** 

If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

### TITLE OF INVENTION

Species-specific PCR Assay for detection of Leishmania Donovani in clinical samples of Kala-Azar

and p	ost Kal	a-Azar Dermal Leishmaniasis
-		SPECIFICATION IDENTIFICATION
The sp	ecificat	ion of which:  (complete (a), (b), or (c))
(a)	[]	is attached hereto.
NOTE:	with a s	llowing combinations of information supplied in an oath or declaration filed on the application filing date specification are acceptable as minimums for identifying a specification and compliance with any one of th elow will be accepted as complying with the identification requirement of 37 C.F.R. Section 1.63:
	declara	"(I) name of inventor(s), and reference to an attached specification which is both attached to the oath o tion at the time of execution and submitted with the oath or declaration on filing;
		"(2) name of inventor(s), and attorney docket number which was on the specification as filed; or
		"(3) name of inventor(s), and title which was on the specification as filed."
		Notice of July 13, 1995 (1177 O.G. 60).
(b)	[x]	was filed on February 27, 2002, [x] as Application No10/086,184 and was amended on (if applicable).
NOȚE:	filing de applica	ments filed after the original papers are deposited with the PTO that contain new matter are not accorded c ate by being referred to in the declaration. Accordingly, the amendments involved are those filed with the tion papers or, in the case of a supplemental declaration, are those amendments claiming matter not assed in the original statement of invention or claims. See 37 C.F.R. Section 1.67.
NOTE:	encompassed in the original statement of invention or claims. See 37 C.F.R. Section 1.67.	

(c)	[]		scribed and claimed in PCT International Application No and as amended under PCT Article 19 on	
		SUPP	LEMENTAL DECLARATION (37 C.F.R. Section 1.67(b))	
	6	complete t	he following where a supplemental declaration is being submi	tted)
	[]	I hereby	y declare that the subject matter of the	
		[]	attached amendment amendment filed on	
	was p applic	art of my/ cation, abo	our invention and was invented before the filing date of the or	ginal
	ACK	NOWLE	DGMENT OF REVIEW OF PAPERS AND DUTY OF CA	NDOR
specifi	I here ication,	by state th including	at I have reviewed and understand the contents of the above-ic the claims, as amended by any amendment referred to above.	lentified
37, Co	I acknode of Fe	iowledge t ederal Reg	he duty to disclose information, which is material to patentabigulations, Section 1.56,	lity as defined in
			(also check the following items, if desired)	
	[]	where the	ch is material to the examination of this application, namely, in the reasonable Examiner would be substantial likelihood that a reasonable Examiner would be substantial likelihood that a reasonable Examiner would be substantial likelihood that a polication to issue as a particular to the substantial between the subs	ld consider it
			in compliance with this duty, there is attached an information statement, in accordance with 37 C.F.R. Section 1.98.	disclosure
			PRIORITY CLAIM (35 U.S.C. Section 119(a)-(d))	
NOTE:	37 C.F.	R. § 1.55 Cla	aim for foreign priority.	
		"(a) An ap foreign ap and (b).	plicant in a nonprovisonal application may claim the benefit of the filing date plications under the conditions specified in 35 U.S.C. 119(a) through (d) and	of one or more prior (f). 172, and 365(a)
		) 4	(1)(i) In an original application filed under 35 U.S.C. III(a), the claim foresented during the pendency of the application,, and within the later of forestual filing date of the application or sixteen months from the fling date of application. This time period is not extendable. The claim must identify the for which priority os claimed, as well as any foreign application for the same having a filing date before that of the application for which priority is claimed.	our months from the of the prior foreign eign application for subject matter and

application number, country (or intellectual property authority), day, month, and year of its filing. The time period in this paragraph does not apply to an application for a design patent.

(ii) In an application that entered the national stage from an international application after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT."

(2) The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. 119(b) or PCT Rule 17 must, in any event, be filed before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by the processing fee set forth in § 1.17(i), but the patent will not include the priority claim unless corrected by a certificate of correction under 35 U.S.C. 255 and § 1.323.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(d) (e)	[x]	no such applications have been filed. such applications have been filed as follows.
NOTE:	Where	item (c) is entered above and the International Application which designated the U.S. itself claimed priorit

check item (e), enter the details below and make the priority claim.

# PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. SECTION 119(a)-(d)

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING DAY, MONTH, YEAR	PRIORITY CLAIMED UNDER 35 USC 119
			[]YES []NO

### CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S) (35 U.S.C. Section 119(e))

35 U.S.C. 119(e)(1) requires that a nonprovisional application be filed within twelve months of the filing date of the provisional application for the nonprovisional application to claim the benefit of the filing date of the provisional application. Under 35 U.S.C. 21(b) and 119(e)(3), if this twelve-month period expires on a non-business day, it is extended to expire on the next business day.

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER	FILING DATE
	<del></del>
	<del></del>

### CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. SECTION 120

[ ] The claim for the benefit of any such applications are set forth in the attached ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART (C-I-P) APPLICATION.

ALL FOREIGN APPLICATION(S), IF ANY, FILED MORE THAN 12 MONTH	<b>IS</b>
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION	

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. Section 120.

### **POWER OF ATTORNEY**

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

(list name and registration number)

JOSEPH H. HANDELMAN, 26179

JULIAN H. COHEN, 20302

JOHN RICHARDS, 31053

WILLIAM R. EVANS 25858

RICHARD J. STREIT, 25765

JANET I. CORD, 33778

PETER D. GALLOWAY, 27885

CLIFFORD J. MASS, 30086

RICHARD P. BERG, 28145

CYNTHIA R. MILLER, 34678

(Declaration and Power of Attorney-page 5 of 8) 1-1

### (Check the following item, if applicable)

- [ ] I hereby appoint the practitioner(s) associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.
- [ ] Attached, as part of this declaration and power of attorney, is the authorization of the above-named practitioner(s) to accept and follow instructions from my representative(s).

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Ladas & Parry 26 West 61<sup>st</sup> Street New York, N.Y. 10023 DIRECT TELEPHONE CALLS TO: (Name and telephone number)

Clifford J. Mass (212) 708-1890

(complete the following if applicable)

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### SIGNATURE(S)

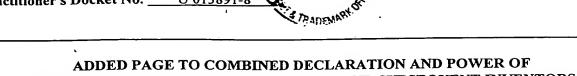
NOTE: Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other document.

NOTE:	Each inventor must be identified by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and by his/her residence, post office address and country of citizenship. 37 C.F.R. Section 1.63(a)(3).				
NOTE:	Inventors may execute separate declarations/oaths provided <u>each</u> declaration/oath sets forth all the inventors. Section 1.63(a)(3) requires that a declaration/oath, inter alia, identify each inventor and prohibits the execution of separate declarations/oaths which each sets forth only the name of the executing inventor. 62 Fed. Reg. 53,131, 53,142, October 10, 1997,				
Full n	ame of sole or first i	nventor	,		
Poona (Giver	m n Name)	(Middle Initial or Name)	SALOTRA Family (Or Last Name)		
Inven	tor's signature <u>(X)</u>	. I Youram			
Date (	(X) Wecember 5,	2002Country of Citizenship	India		
Resid	ence <u>C 145, Sarvoday</u>	a Enclave, New Delhi 110017, India	<u> </u>		
Post (	Office Address	(Same as above)			
	•		`.` <b>`</b> .		
Full 1	name of second joint	inventor, if any	CDEENIN/A C		
`	n Name)	(Middle Initial or Name)	- <u>SREENIVAS</u> Family (Or Last Name)		
	ntor's signature <u>(X)</u>	Comment of the commen	T. 1:-		
		002. Country of Citizenship	India		
		ya Enclave, New Delhi 110017, Indi	a		
Post	Office Address	(Same as above)			
Full	name of third joint i	nventor, if any			
Greg (Give	ory en Name)	P. (Middle Initial or Name)	POGUE Family (Or Last Name)		
· Inve	ntor's signature <u>(X)</u>				
Date	(X)	Country of Citizenship	United States of America		
Resi	dence <u>419 Trillick Ct</u>	., Vacaville, California 95688			
Post	Office Address	(Same as above)	· · · · · · · · · · · · · · · · · · ·		

# (check proper box(es) for any of the following added page(s) that form a part of this declaration)

[x]	Signature for fourth and subsequent joint inventors. Number of pages addedl
	* * *
( )	Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. Number of pages added
	* * *
[]	Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 C.F.R. Section 1.47. <i>Number of pages added</i>
	* * *
[]	Added page for signature by one joint inventor on behalf of deceased inventor(s) where legarepresentative cannot be appointed in time. (37 C.F.R. Section 1.47)
	* * *
[]	Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (C-I-P) application.  [ ] Number of pages added
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[]	Authorization of practitioner(s) to accept and follow instructions from representative.
	(If no further pages form a part of this Declaration, then end this Declaration with this page and check the following item)
•	[ ] This declaration ends with this page.

Practitioner's Docket No.	<u>U 013891</u> -
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### ATTORNEY FOR SIGNATURE BY FOURTH AND SUBSEQUENT INVENTORS

Full name of fourth joint in	nventor, if any	
Hiralal (Given Name)	(Middle Initial or Name)	NAKHASI . Family (Or Last Name)
Inventor's signature (X)	· · · · · · · · · · · · · · · · · · ·	
Date (X)	Country of Citizenship	United States of America
Residence 8504 Potomac	School Terrace, Potomac, Marylan	d 20854
		,
Full name of fifth joint inv	rentor, if any	
(Given Name)	(Middle Initial or Name)	Family (Or Last Name)
Inventor's signature		
_		
	,	
	: + _	• :
Full name of sixth joint in	ventor, if any	
(Given Name)	(Middle Initial or Name)	Family (Or Last Name)
Inventor's signature		
Date	Country of Citizenship	•
Residence		
Post Office Address		

(Added Page to Combined Declaration and Power of Attorney for Signature by Fourth and Subsequent Inventors page 1 of 1) 1-2